

REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 1-13 and 42-55 will be pending in this application. Responding now to the two rejections made in the current Official Action:

Double patenting

Applicants do not accept the obviousness type double patenting rejection over pSiMedica's US Patent No. 7,763,277 based in part upon the information already included in the specification of the present application.

The Examiner argues that the present claims are not patentably distinct from the claims of US 7,763,277 as this discloses porous silicon impregnated with beneficial substance, at a concentration of between 1 and 90% and at a pore depth of between 0.035 to 1000µm.

This assertion is not well-founded and applicants draw the Examiner's attention to the discussion on page 4 of the present specification of the PCT published application (WO 99/53898) from which US 7,763,277 derives. As pointed out in the present specification, the delivery system of WO 99/53898 would be inappropriate for delivering high doses of organic compounds -- although loading of porous silicon implants with various metals or compounds of metals by a method involving melting a salt of the metal on the surface of a sample of porous silicon is discussed in WO 99/53898, it is suggested that such a method would not be applicable in the case of large organic drug molecules as thermal degradation would be expected to occur when melting takes place.

There would be no motivation to look to the method of WO 99/53898 /US 7,763,277 for the delivery of high doses of beneficial organic compounds and applicants therefore submit that this cited reference does not render the present invention obvious.

US 7,763,277 is concerned primarily with implants for administering micronutrients or microminerals (see column 1, line 16, also column 4, lines 12-13), particularly with delivering low payloads (see column 1, line 59).

As is made clear in the discussion in column 4, lines 1-14 of US 7,763,277, providing a beneficial substance in a porous silicon implant is appropriate for delivering substances, such as micronutrients or microminerals, which do not need to be delivered at high doses -- dry payloads of tens to hundreds of micrograms of substance up to a few milligrams are contemplated (column 4, lines 9-11), rendering the delivery system unsuitable for the delivery of macronutrients or

macro dose drugs. Restrictions on the physical size of the payload for implants are stated to restrict that use, in practice, to substances, such as microminerals, which are not required at high level (column 13, lines 17-20). Furthermore, no examples of the delivery of organic substances, let alone the delivery of high loadings of organic substances, are provided in US 7,763,277.

Based on the disclosure of US 7,763,277 the average skilled person would have no reason to consider impregnating porous silicon with any beneficial substances other than micronutrients or microminerals and certainly would have no reason to contemplate using an impregnated porous silicon delivery system to provide high dose loadings of a beneficial organic substance to a subject as in the present invention.

The subject matter of present claims 1-13 is not obvious over the disclosure of US 7,763,277.

Anticipation

Turning to the rejection under 35 USC §102(c) based on US 7,763,277, applicants submit that the present invention is not anticipated by US 7,763,277.

Not only is there no specific exemplification in US 7,763,277 of porous silicon impregnated with a beneficial *organic* substance to a pore depth and in an amount as recited in present claim 1, but US 7,763,277 actually teaches away from making such an invention (“... restrictions on the physical size of the drug payload for implants will restrict ... practical use to delivering microminerals or other substances which are not required at high levels...”, see column 13, lines 17-19). The suggestion at column 13, lines 23-24, that the delivery system of US 7,763,277 does not represent a practical solution to macro-drug delivery further supports this view.

Applicants submit, therefore, that the average skilled reader would not interpret the references in US 7,763,277 to beneficial substances, depth and amounts cited by the Examiner as constituting a description of the present invention.

In order to advance prosecution and to further distinguish the present invention from US 7,763,277, applicants submit herewith new claims 42-55 in which the definition of beneficial organic substances in new claim 42 is restricted to organic substances with greater than 5 carbon atoms. New claim 43 specifies antibodies, peptides and genetic constructs. Basis for restriction can be found in the present specification at page 10, lines 15-20.

All outstanding issues have been addressed and this application is in condition for allowance. Should any minor issues remain outstanding, the Examiner should contact the undersigned at the telephone number listed below so they can be resolved expeditiously without need of a further written action.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 14-1140.

Respectfully submitted,

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